



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

October 17, 2002

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 5813-TO
CDQ
DP Barcode: D285814
Case No: 67431

To: Velma Noble PM 31 / Zenobia Jones, Team Reviewer
Regulatory Management Branch I
Antimicrobials Division (7510C)

From: Robert A. Turpin, Scientist *R.T.*
Chemistry/Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

[Signature]
10/25/02

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: The Clorox Co.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
n-Alkyl (C ₁₄ , 60%; C ₁₆ , 30%; C ₁₂ , 5%; C ₁₈ , 5%) dimethyl benzyl ammonium chloride	0.184
n-Alkyl (C ₁₂ , 68%; C ₁₄ , 32%) dimethyl ethylbenzyl ammonium chloride	0.184
<u>Other Ingredient(s):</u>	99.632
Total:	100%

BACKGROUND: The applicant has submitted an application for the registration of its product, CDQ, a pre-moistened wipe. The applicant is claiming a "Me-Too" similarity to the registered product, Spruce-Ups, EPA Reg. No. 5813-58.

RECOMMENDATIONS (PSB findings):

The acute toxicity profile for Reg. No. 5813-TO is currently:

acute oral toxicity	IV	Acceptable
acute dermal toxicity	IV	Acceptable
acute inhalation toxicity	IV	Waived
primary eye irritation	III	Acceptable
primary skin irritation	III	Acceptable
dermal sensitization	Non-sensitizer	Acceptable

LABELING:

1. The Signal Word is CAUTION.
2. The Precautionary Statements and First Aid Statements are acceptable.
3. The Storage and Disposal Statements are acceptable.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§ 81-1, 870.1100)

Product Manager: Velma Noble
MRID No.: 441345-05

Reviewer: R. Turpin
Study Completion Date: January 3, 1989
Report No.: MB 88-9331A

Testing Laboratory : MB Research Laboratories, Inc.
Authors : Daniel R. Cerven

Quality Assurance (40 CFR §160.12): Statement provided.

Test Material: Pine Sol Spruce-Ups

Species: Rat

Age: 8 weeks

Weight: Males, 205-277 grams; Females, 201-231 grams

Source: Ace Animals

Conclusion:

1. LD₅₀ (mg/kg):

Males = >5,000 mg/kg

Females = >5,000 mg/kg

Combined = >5,000 mg/kg

2. The estimated LD₅₀ is >5,000 mg/kg

3. Tox. Category: IV

Classification: Acceptable

Procedure (Deviations from §81-1): None noted.

Results:

Dosage (mg/kg)	(Number Deaths/Number Tested)		
	Males	Females	Combined
5,000 mg	0/5	0/5	0/10

Observations: There were no mortalities. Physical signs of chromorhinorrhea, yellow nasal discharge, apparent emaciation, ptosis and soiling of the anogenital area were noted during

the observation period. Body weight changes were normal in 9/10 animals. One male lost weight in the first week of study.

Gross Necropsy: Necropsy results were normal in 7/10 animals. Hydronephrosis of the kidneys was noted in two animals and soiling of the anogenital area was observed in one animal.

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)

Product Manager: Velma Noble
MRID No.: 411345-07

Reviewer: R. Turpin
Study Completion Date: December 27, 1988
Report No.: MB 88-9331C

Testing Laboratory: MB research Laboratories, Inc.
Author: Daniel R. Cerven

Quality Assurance (40 CFR §160.12): Statement provided.

Test Material: Pine Sol Spruce-Ups
Dosage: 0.5 ml

Species: Rabbit

Age: 8 weeks

Sex:

Weight: 2.0 to 3.0 kg

Source:

Summary:

1. **Toxicity Category:** III
2. **Classification:** Acceptable

Procedure (Deviations From §81-5): None noted.

Results: All animals showed erythema and edema. Two animals were asymptomatic at the 24 hour observation. Others exhibited varying degrees of symptoms through day seven of the observation period.

Special Comments: None.

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6, 870.2600)

Product Manager: Velma Noble
MRID No.: 411345-08

Reviewer: R. Turpin
Study Completion Date: April 21, 1988
Report No.: 89-6626A

Testing Laboratory: Biosearch Incorporated
Author: Donna M. Daniels

Quality Assurance (40 CFR §160.12): Statement provided.

Test Material: Pine Sol Spruce-Ups

Positive Control Material: 1-chloro-2,4-dinitrobenzene

Species: Guinea pig

Weight: 300 to 500 grams

Age: N/A

Source: Buckshire Corp.

Method: Modified Buehler Method

Summary:

1. **This Product is not a dermal sensitizer.**
2. **Classification:** Acceptable

Procedure (Deviation From §81-6): None noted.

Procedure: Twelve animals were prepared and treated with a concentration of 50% v/v of the test material in deionized water. A 0.5 ml portion was applied to the test site and covered with gauze and wrapped with an impervious material. The patch was removed after 6 hours. After 24 hours the treatment sequence was repeated three times weekly for a total of nine applications. After a two week rest period the animals were treated with a challenge dose.

Results: The test material was determined to be a non-sensitizer.

ACUTE TOX ONE-LINER

1. PC CODE: 69104/69154
2. CURRENT DATE: October 17, 2002
3. TEST MATERIAL: Pine Sol Spruce-Ups

Study/Species/Lab/ Study#/Date	MRID No.	Results	Tox. Cat.	Core Grade
acute oral toxicity /Rat/MB Research Lab. Inc./MB 9331A/01-03-1989	411345-05	LD ₅₀ (mg/kg) = >5,000 mg/kg	IV	A
acute dermal toxicity /	456809-01	LD ₅₀ (mg/kg) = >2,000 mg/kg	IV	A
acute inhalation toxicity /	Waived	LC ₅₀ (mg/L)	IV	A
primary eye irritation /	456809-02	Mild irritant	III	A
primary skin irritation / Rabbit/MB Research Lab. Inc./MB 88-9331C/12-27-1988	411345-07	Minor irritation	III	A
dermal sensitization / Guinea pig/Biosearch Inc./89-6626A/ 04-21-1988	411345-08	Non- sensitizer	---	A

A = Acceptable
U = Unacceptable
S = Supplementary
V = self-Validated